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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,786	04/04/2001	Gerald W. Mills	723.035US1	1321

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EXAMINER	
CHENG, JACQUELINE	
ART UNIT	PAPER NUMBER
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/825,786	MILLS ET AL.	
	Examiner	Art Unit	
	Jacqueline Cheng	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-21,23-26 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-21,23-26 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed September 5, 2006 have been fully considered but they are not persuasive. The applicant argues that there is no motivation to combine the control module in Franck with the separated actuator outside an imaging region from the local adjustment device within the imaging region of Truwit as recited in claim 10. The examiner respectfully disagrees with the applicant. Truwit discloses that by using the remote actuation control device 3000 allows the surgeon to manipulate the local adjustment device which may not be accessible while the patient and the local adjustment device are located within the imaging/scanning environment. Having the actuator separated and outside the imaging region saves time for the surgical procedure, and lessens the exposure time of the patient to any detrimental aspects of the scanning environment. It would also be obvious to have the actuator outside the imaging region so that the surgeon does not have to be exposed to the scanning environment at all. Franck also keeps the surgeon from exposure to the scanning environment through the remote actuation of the local adjustment device/actuator through interacting with the manipulator 2750.

2. The applicant also argues that neither Truwit, Franck or their combination, teaches a multi-axis local adjustment device with a detachable actuator as recited in claim 20. The examiner respectfully disagrees with the applicant. Franck discloses that in the aligning of the guidance fixture, the goal of the alignment procedure is to make line 1040 of fig. 14b-c coincident with the intersection of planes 1020 and 1022. The alignment procedure is carried out in a series of two motions, each of which is constrained to one degree of freedom. These degrees

of freedom are in two different directions or multi-axial, as they must be moved in two different planes to be coincident with the intersection of the two planes.

3. Therefore the examiner maintains the rejection from the previous office action dated May 3, 2006 and repeated below.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 10-17, 20, 21, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Franck et al*** (SU 6,529,765 B1) in view of ***Truwit*** (US 6,206,890 B1).

Franck et al substantially anticipate all claimed features in claims 10-17, 20, 21, 30, and 31.

Claims 10 and 20: Franck et al disclose a method and apparatus where an alignment system as shown in figures 3, 5, 7, 9, and 10 where the system comprises a base 330affixed to a patient's surface, a insertion guide 710 (in figure 9) having an opening and insertion axis through the opening, an adjustable joint attached to a distal end of the insertion guide, and coupled to the base plate 724, a local adjustment device attached to the adjustable joint 840, an actuator coupled to the local adjustment device, and a control module 580 in remote communication with the actuator and in communication with the imaging device 560 to alignment the insertion axis with the target location (col. 3, line 65 – col. 4, line 65; col. 7, line 57 – col. 8, line 47; col. 8, line 50 –

col. 9, line 6; col.11, line 40 – col. 12, line 41). Although, Franck et al do not specifically disclose remote actuator spaced apart from the local adjustment device to locate the actuator outside an imaging region of the imaging device while the local adjustment is within the imaging region of the imaging device, such disclosure is well known in the art. For example, Truwit shows in figures 30 to 32 where mechanical remote actuation and control device 3000 which includes the actual trajectory guide 3001 which is attached to a patient and a second trajectory guide spaced apart remotely from the patient and imaging device (col. 14, line 31 – col. 15, line 20). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Truwit's remote actuator with Franck et al's device above as described above.

Claim 11: Franck et al disclose the control module as described above is a workstation. However, the miniaturization of computer (microcomputer) is purely a design choice since the control function of the control module does not change with the size of the control module.

Claim 12: Franck et al disclose that the image-guided procedure such as one described above can be used with variety of medical imaging system including MRI device (col. 1, lines 43-50).

Claims 13-15: Franck et al disclose fiducial markers 340 where the markers provide first reference coupled to the insertion guide to locate the insertion axis in 3D space relative to the patient (col. 8, lines 3-31).

Claims 16 and 17: Franck et al disclose a reference device 730 in which it provides LED to locate the insertion axis in 3D space relative to the patient (col. 12, lines 1-13).

Claim 21: Franck et al as shown in figures 3, 5, 7, and 9 where the coupling at he base includes attached the base directly to the skull of the patient (col. 8, lines 5-11).

Claims 29 and 32: Franck et al do not explicitly disclose in writing the structure of the actuator being a ball and socket joint. In figures 11, 17c, and 19, Franck et al illustrates socket join with round structure 914 in round shape. Although, Frank et al's disclosure is silent in ball and socket joint, it would be obvious to view figure 11 as ball and socket without complete drawing of 914 where ball and socket joint is used in the art as evident by Truwit's (6,206,890 B1) use of the same structure for the insertion guide (see figure 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Franck et al with the ball and socket joint actuator as disclosed by Truwit to provide accurate actuation of the insertion guide as disclosed by Franck et al.

Claims 30 and 31: Franck et al further disclose the local adjustment described above where it includes slide coupled to the insertion guide 850 as shown in figure 10.

6. Claims 18, 19, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Franck et al*** and ***Truwit*** as applied to claims 10 and 20 above, and further in view of ***Lee et al*** (US 3,893,449).

Franck et al and Truwit substantially disclose of all claimed invention in claims 18, 19, and 23-26. However, Franck et al do not disclose rotary motor coupled to the local adjustment device and the control of the device via potentiometer. Lee et al discloses of an imaging device placed on a patient with remote control of the device to align the imaging device to an appropriate location. Lee et al also teaches that the location of the medical device such as ultrasound is referenced to identify the position using potentiometer (col. 1, line 59 – col. 2, line

11). Lee et al also disclose in figures 2 and 11 where the control mechanism includes pin joint actuator with rotary motor with rotating cable drive (col. 5, lines 36-64). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Franck et al's aligning imaging device to teachings of Lee et al's position referencing system to achieve the claimed invention.

Conclusion

7. This is a continuation of applicant's earlier Application No. 09/825,786. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER